IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

In re: Atrium Medical Corp. C-Qur Mesh Products Liability Litigation
C.A. No. 16-md-2753-LM, MDL No. 2753

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through the undersigned lead counsel, bring this Master Long Form Complaint as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. Individual Plaintiffs will incorporate this Master Long Form Complaint by reference in their Short Form Complaints.

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1. Plaintiffs include men and women who had one or more of Defendants' hernia mesh products listed in Paragraph 19 of this Master Long Form Complaint (hereinafter "Master Complaint") inserted in their bodies to treat hernia(s). Plaintiffs also include their spouses, as well as others with standing to file claims arising from the hernia mesh products described herein.

DEFENDANTS

1. Atrium Medical Corporation ("Atrium") is incorporated under the laws of Delaware. At all pertinent times, Atrium's manufacturing and support facilities were located in Hudson, NH. Atrium is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including C-QUR Mesh (hereinafter "C-QUR" or "product" or "mesh").

2. Maquet Cardiovascular US Sales, LLC ("Maquet") is a limited liability company organized under the laws of New Jersey, with its principal place of business located at 45 Barbour

Pond Drive, Wayne, NJ 07470. Since October of 2011, Atrium has operated within, and as a business unit of, Maquet.

3. Getinge AB ("Getinge") is a Swedish corporation, organized under the laws of Sweden with its principal place of business in Sweden. At all times pertinent hereto, Maquet was a wholly-owned subsidiary of Getinge AB.

4. Getinge is a holding company, the purpose of which is to coordinate the administration, finances and activities of its subsidiary companies, including Maquet and its business unit/division Atrium, and to act as managers and to direct or coordinate the management of its subsidiary companies or of the business, property and estates of any subsidiary company, including Maquet and its business unit/division Atrium.

5. The financial accounts of Maquet and its business unit/division Atrium are consolidated within those of Getinge.

6. In 2011, Getinge acquired Atrium through a merger. When Getinge acquired Atrium through a merger, it acquired Atrium's assets and assumed Atrium's liabilities.

ATRIUM MEDICAL INC.

Acquired net assets and goodwill in connection with the acquisition, SEK m	Assets and liabilities at the acquisition date	Adjustment to fair value	Fair value	Description
Intangible assets	–	1,602	1,602	On 1 November 2011, the US-based company Atrium Medical was acquired. The total acquisition price amounted to about USD 680 m (SEK 4,447 m).
Tangible assets	78		78	
Financial assets	142		142	
Inventories	145		145	
Receivables	174		174	
Cash and cash equivalents	148		148	
Provisions	–	-641	-641	Goodwill that arose in conjunction with the transaction is attributable to the expected future ancillary sales trend. Amortisation expenses for acquired intangible assets amount to about SEK 150 m per year. The company has been included in Getinge's sales and operating earnings since 1 November 2011.
Current liabilities	-316		-316	
	371	961	1,332	
Goodwill			3,263	
Total acquisition with cash and cash equivalents			**4,595**	
Net outflow of cash and cash equivalents due to acquisition				
Cash and cash equivalents paid for the acquisition			4,595	
Cash and cash equivalents in the acquired company at the acquisition date			-148	
			4,447	

7. Since the merger, Atrium has operated as a division/business unit of Getinge subsidiary Maquet.

8. Getinge and Maquet expressly or impliedly assumed Atrium's liabilities, including its pre-acquisition liabilities and, therefore, Getinge and Maquet are liable as Atrium's successors.

9. Additionally, the post-merger actions of Getinge and Maquet demonstrate a mere continuation of Atrium's product line and business enterprise. Accordingly, Getinge and Maquet are liable as Atrium's successors.

10. Getinge is the owner of Atrium, including the rights to Atrium's C-QUR patents. Maquet has direct control over Atrium's activities. Following the merger with Atrium, Getinge and Maquet have continued to manufacture and sell the same defective C-QUR product line as Atrium under the same brand so as to hold themselves out to the public as a mere continuation of Atrium. Getinge and Maquet have benefitted, and continue to benefit, from Atrium's brand and goodwill. The Maquet Getinge Group website (www.maquet.com) lists the C-QUR product as one of Maquet Getinge Group's "biosurgery" products. Maquet Website, C-QUR Mesh, http://www.maquet.com/us/products/C-QUR-mesh/?ccid=231 (last visited Apr. 14, 2017).

11. Defendants Getinge and Maquet represent that Atrium had become "part of 'Maquet Getinge Group.'" *See* Atrium Website, http://www.atriummed.com (last visited Apr. 14, 2017) (stating that "Atrium is now part of Maquet Getinge Group"); *see also,* Atrium Website, Press Release Archive, *Atrium Medical Agrees to be Acquired by Getinge Group for $680* Million, http://www.atriummed.com/News/atriumnews.asp?articleid=60&zoneid=1 (Oct. 3, 2011) (last visited Apr. 14, 2017) (press release detailing the acquisition of Atrium by Maquet Getinge Group).

12. Getinge and Maquet are also liable for any acts and/or omissions by or through Atrium because it is merely the alter ego, or an instrumentality of Getinge and Maquet.

13. Publicly-available information, published by Getinge and Maquet, indicates that the Atrium division is being phased out of existence, yet the product line and business is not. Getinge and Maquet now represent themselves as the owners and/or sellers of the C-QUR product line and Atrium is oft referred to as a former designation. *See e.g.*, Maquet Website, C-QUR Mesh, *https://www.maquet.com/us/workspaces/operating-room/?filter=231* (last visited Apr. 14, 2017) (showing the C-QUR products on the Maquet website, without reference to Atrium, and including in the available product brochures); *see also*, Maquet Website, Contact Us, https://www.maquet.com/us/contact/ (last visited Apr. 14, 2017) (stating that Atrium Medical was the former contact and the proper contact is now Vascular Systems, which uses a "getinge.com" email address, specifically: VSpurchaseorders@getinge.com).

14. Following the merger, Atrium was so organized and controlled and its business conducted in such manner as to make it merely an alter ego or business conduit of Getinge and Maquet. Because Atrium's assets and capital are subject to the ownership and control of Maquet and Getinge, Atrium is undercapitalized, and the failure to disregard Atrium's corporate form would result in the inequitable and unjust result that Plaintiffs may be unable to satisfy any judgment ultimately obtained against Atrium. Atrium acts as an agent for Getinge and Maquet. Maquet, Getinge and Atrium combine their property and labor in a joint undertaking for profit, with rights of mutual control.

15. Maquet and Getinge, directly and/or through the actions of their Atrium division and business unit, are and/or have, at all pertinent times, been responsible for the research, development, testing, manufacture, production, packaging, labeling, marketing, promotion, distribution and/or sale of C-QUR Mesh. Maquet, Getinge, and Atrium shall be referred to hereinafter, collectively, as "Defendants."

16. Defendants are individually, jointly and severally liable to Plaintiffs for damages resulting from the Defendants' design, manufacture, marketing, packaging, labeling, distribution, sale and placement of its defective mesh products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

17. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

18. At all times material to this action, Defendants have designed, patented, manufactured, packaged, labeled, marketed, and sold and distributed a line of C-QUR hernia mesh products. These products were designed primarily for the purposes of treating hernias. These products share common design elements and common defects. Moreover, these products were cleared for sale in the U.S. after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

19. The products known as C-QUR, C-QUR Mosaic, C-QUR Edge, C-QUR TacShield, C-QUR Lite Mesh V-Patch, and C-QUR Mesh V-Patch, as well as many variations of these products and any unnamed C-QUR mesh products designed and sold for similar purposes are collectively referenced herein as "Defendants' Hernia Mesh Products," "C-QUR Mesh," or "the Products."

VENUE AND JURISDICTION

20. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. §1332(a), in that, in each of the constituent actions, there is complete diversity among Plaintiffs and Defendants, and the amount in controversy exceeds $75,000.

21. Defendants have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

22. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(b)(2), venue is proper in said district.

23. Further, venue is proper in this Court pursuant to 28 U.S.C. 1391 by virtue of the fact that Defendants' products are produced, sold to and consumed by individuals in the State of New Hampshire, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

24. Further, Defendants have and continue to conduct substantial business in the State of New Hampshire and in this District, distribute Hernia Mesh Products in this District, receive substantial compensation and profits from sales of Hernia Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

25. Defendants conducted business in the State of New Hampshire through sales representatives conducting business in the State of New Hampshire, and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or

selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in New Hampshire.

26. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of New Hampshire, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

FACTUAL BACKGROUND

27. Defendants' C-QUR Mesh was designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed by Defendants at all relevant times herein.

28. Getinge and Maquet were, at all times relevant hereto, responsible for the actions of Atrium and exercised control over Atrium's functions specific to the oversight and compliance with applicable safety standards relating to, and including C-QUR Mesh sold in the United States. In such capacity, they committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Their misfeasance and malfeasance caused Plaintiffs to suffer injury and damages.

29. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, packaging, promotion, distribution and sale of C-QUR Mesh, as well as providing the warnings and instructions concerning the product.

30. Among the intended purposes for which Defendants designed, manufactured, marketed, and sold C-QUR Mesh was for use by surgeons for hernia repair surgeries—the purpose for which the C-QUR Mesh was implanted in the Plaintiff named in the Short Form Complaint.

31. Defendants' Hernia Mesh Products are designed, intended, and utilized for permanent implantation in the human body.

32. Defendants represented to Plaintiffs and Plaintiffs' physicians that C-QUR Mesh was a safe and effective product for hernia repair and for permanent implantation in humans.

33. Defendants failed to perform and/or rely on adequate testing and research in order to determine and evaluate the risks and benefits of the C-QUR Mesh.

34. Defendants' C-QUR Mesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the C-QUR Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including, but not limited to: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

35. The C-QUR Mesh was manufactured from polypropylene, and has a unique Omega 3 fatty acid gel coating derived from fish oil (hereinafter "Omega 3 coating"), which is not used in any other hernia repair product sold in the United States.

36. Defendants represented the Omega 3 coating would prevent or minimize adhesion and inflammation, and facilitate incorporation of the mesh into the body, but it did not. Instead, the Omega 3 coating prevented adequate incorporation of the mesh into the body causing an intense inflammatory and chronic foreign body response, that resulted in an adverse tissue reaction,

including damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue, and improper healing.

37. When affixed to the body's tissue, the impermeable Omega 3 coating of the C-QUR Mesh prevents fluid escape, which leads to seroma formation, and which, in turn, can cause infection or abscess formation, and other complications.

38. The Omega 3 coating provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

39. The Omega 3 coating of Defendants' C-QUR Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications, such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

40. Defendants knew or should have known of the cytotoxic and immunogenic properties of the Omega 3 coating of the C-QUR Mesh prior to introducing it into the stream of commerce.

41. Defendants failed to adequately test the effects of the Omega 3 coating on their C-QUR Mesh in animals and humans, both before and after the product entered the stream of commerce.

42. When the Omega 3 coating is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, can become adhered to organs, cause incarceration of organs, and, among other things, can result in severe infections, abscess(es), and/or fistula formation.

43. Defendants knew or should have known that the Omega 3 coating disrupts and/or degrades eventually, allowing the uncoated mesh to directly contact the adjoining tissue and viscera.

44. Feasible and suitable alternative procedures and instruments to the C-QUR Mesh, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all relevant times.

45. Defendants failed to design and establish a safe, effective procedure for removal of the C-QUR Mesh; thus, in the event of a failure, injury, or other complication, it is impossible to easily and safely remove the C-QUR Mesh.

46. Due to serious problems with sterilization and quality control in the Atrium manufacturing facilities, the Omega 3 coating was not uniformly applied to the C-QUR Mesh devices.

47. The Omega 3 coating applied to the mesh caused or contributed to the propensity of the C-QUR Mesh to roll, curl and deform upon insertion into the body, intensifying the inflammatory and foreign body response to the mesh, and exacerbating the lack of adequate incorporation and improper healing response, and potential for adhesion.

48. The Omega 3 coating was also unreasonably susceptible to deterioration and degradation, and even separation from the polypropylene mesh, both in the packaging and inside the body.

49. The Omega 3 coating of the C-QUR Mesh also failed to conform to the manufacturer's specifications in terms of shelf-life, thickness, durability, quality, and biochemical properties.

50. Defendants had sole access to material facts concerning the defective nature of the Products and their propensity to cause serious and dangerous side effects.

51. Upon information and belief, Defendants adjusted the threshold for reporting and recalling the C-QUR mesh due to non-conformities and adverse event reports, resulting in a large number of injurious events, deemed by Defendants to be acceptable, to go unreported.

52. Upon information and belief, Defendants made misleading statements to physicians about potential adverse events and attempted to convince physicians of alternative causes other than the C-QUR Mesh.

53. Upon information and belief, Defendants omitted information regarding potential adverse events in discussions with physicians.

54. Upon information and belief, Defendants "stealth recalled" multiple types of C-QUR Mesh that were experiencing high levels of adverse events by simply halting production of certain types of C-QUR Mesh without notifying consumers or physicians of the recall or high levels of adverse events.

55. Upon information and belief, Defendants manipulated altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the C-QUR Mesh and/or diminish adverse events.

56. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the C-QUR Mesh, but did not readily disclose this information.

57. Defendants marketed and sold the C-QUR Mesh to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to healthcare providers at medical conferences, hospitals, and private offices, as well as the provision of valuable

benefits to healthcare providers. Defendants further utilized documents, patients, brochures, and websites.

58. Defendants have, at all times relevant hereto, provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing C-QUR Mesh, thereby increasing sales. This has led to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

59. Upon information and belief, Defendants have been notified about the widespread catastrophic complications associated with the C-QUR Mesh by leading hernia repair specialists, surgeons, hospitals, patients, internal consultants, and/or employees.

60. Despite notice and knowledge of complications, not a single C-QUR Mesh has been formally recalled from the market.

61. Defendants have misrepresented the efficacy and safety of the C-QUR Mesh, through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

62. Defendants' C-QUR Meshes continues to be marketed to the medical community and to patients as safe, effective, reliable medical devices, implanted by safe and effective surgical techniques for the treatment of hernia repair and soft tissue repair, and as safer or more effective as compared to the traditional products and procedures, including competing hernia mesh products.

63. In reliance on Defendants' representation, Plaintiffs' physicians were induced to, and did use, the C-QUR Mesh.

64. Defendants' C-QUR Meshes were, at all times, utilized and implanted in a manner foreseeable and/or intended by Defendants.

65. The C-QUR Mesh implanted into each of the Plaintiffs was in the same or substantially similar condition as when it left Defendants' possession, and/or in the condition directed by and expected by Defendants.

66. As a direct and proximate result of having the C-QUR Mesh implanted, Plaintiffs have been severely and permanently injured.

67. These manufacturing and design defects associated with the C-QUR Mesh were directly and proximately related to the injuries suffered by the Plaintiff named in the Short Form Complaint.

68. Neither Plaintiffs nor their implanting physicians were adequately warned or informed by Defendants of the defective and dangerous nature of C-QUR Mesh, including the risks specifically associated with the Omega 3 coating. Moreover, neither Plaintiffs nor his/her implanting physicians were adequately warned or informed by Defendants of the risks associated with the C-QUR Mesh.

69. The C-QUR Mesh implanted in the Plaintiff named in the Short Form Complaint failed to reasonably perform as intended. The mesh caused serious and permanent injuries, resulting in the need for additional treatment, including additional corrective surgery or surgeries.

70. Plaintiffs' severe adverse reactions, and the necessity for additional treatment, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product.

71. Plaintiffs have suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe injury, including scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical bills and other expenses, resulting from

the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

72. The Plaintiff named in the Short Form Complaint, in the existence of due diligence could not have reasonably discovered the Defendants' wrongful conduct and the cause of his/her injuries, including, but not limited to, the defective design and/or manufacturing of the C-QUR until a date within the applicable statute of limitations.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

73. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, which include the Defendants' intentional concealment from Plaintiffs and the general public that the C-Qur Mesh is defective, while continually marketing the Mesh with the defects described herein.

74. Given the Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which the Defendants had exclusive control – and because Plaintiffs could not reasonably have known that the C-Qur Mesh was defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

COUNT I: NEGLIGENCE

75. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

76. At all relevant times, Defendants had a duty to individuals, including the Plaintiff named in the Short Form Complaint, to exercise reasonable and ordinary care in the manufacture, design, packaging, labeling, instructions, warnings, sale, marketing, and distribution of the

Defendants' C-QUR Mesh, as well as in the recruitment and training of physicians to implant the C-QUR Mesh.

77. Defendants breached their duty of care to the Plaintiffs, as aforesaid, in the manufacture, design, packaging, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the C-QUR Mesh.

78. Defendants breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to the patients in whom the Products were implanted, including the Plaintiff named in the Short Form Complaint;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to patients in whom the Products were implanted, including the Plaintiff named in the Short Form Complaint;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to patients in whom the Products were implanted, including the Plaintiff named in the Short Form Complaint;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to patients in whom the Products were implanted, including the Plaintiff named in the Short Form Complaint; and/or

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

79. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Biomaterial issues with the design of the Products, including the use of the Omega 3 coating, which decreases the PH in the abdominal cavity, carries a high rate of infection and prevents integration of the mesh. The use of Omega 3 results in injuries, including, but not limited to, infection, adverse tissue reactions, and recurrence;

c. Biomechanical issues with the design of the Products, including the propensity to shrink or contract inside the body, which causes surrounding tissue to become fibrotic and contract, and results in injury; and/or

d. The propensity of the Products to degrade and fragment inside the body, which causes a chronic inflammatory and fibrotic reaction, resulting in injury over time.

80. Defendants also negligently failed to warn or instruct Plaintiffs or their physicians of subjects, including, but not limited to, the following:

a. The cytotoxicity, immunogenic, and biologically incompatible nature of the Omega 3 coating;

b. The unusually high rate of infection associated with the Omega 3 coating.

c. The propensity of the Omega 3 coating to decrease the PH of the abdominal cavity and/or the blood;

d. The propensity of the Products to roll, curl, and deform upon insertion into the body;

e. The Products' propensities for deterioration, degradation, and fragmentation;

f. The lack of quality control with regard to the uniformity of the Omega 3 coating;

g. The Products' propensity to shrink or contract within the body;

h. The risk of chronic inflammation resulting from the Products;

i. The risk of chronic infections resulting from the Products;

j. The need for corrective surgery to adjust, remove, or revise the Products;

k. The frequency, severity, and duration of complications associated with the Products;

l. The Products defects described herein;

m. Treatment with the Products is no more effective than feasible, available alternatives;

n. Treatment with the Products exposes patients to more risk than feasible, available alternatives;

o. Use of the Products put patients at a greater risk of requiring additional surgery than feasible, available alternatives;

p. Use of the Products makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives; and/or

q. Removal of the Products due to complications may significantly impair the patients' quality of life and may not result in complete resolution of their injuries.

r. Inability to remove Products after injury, which increased risk of future injuries.

81. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, packaging, labeling, warnings, instructions, sale, marketing, distribution

and recruitment and training of physicians to implant the C-QUR Mesh would cause foreseeable harm, injuries, and damages to individuals implanted with C-QUR Mesh, including the Plaintiff named in the Short Form Complaint.

82. Defendants knew, or in the exercise of reasonably care should have known, that the C-QUR Mesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injury patients in whom C-QUR mesh was implanted. Defendants knew or should have known that Plaintiffs and their physicians were unaware of the dangers and defects inherent in the C-QUR Mesh.

83. As a direct, proximate, and foreseeable result of the Defendants' negligence, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

84. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

85. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein:

86. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the C-QUR Mesh implanted into Plaintiffs. The C-QUR Mesh was defective in its design in that, when it left the hands of Defendants, it was not safe for its anticipated use and safer feasible alternative designs existed that could have been utilized by Defendants. A reasonably prudent medical device manufacturer would not have placed the C-QUR mesh with its defective design into the stream of commerce.

87. The C-QUR Mesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiffs.

88. Defendants expected and intended the C-QUR Mesh to reach users such as the Plaintiff named in the Short Form Complaint in the condition in which the product was sold.

89. The implantation of the C-QUR Mesh in Plaintiffs was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured, and sold the Products.

90. The C-QUR Mesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the mesh were more dangerous than reasonably prudent consumers, such as Plaintiffs and/or their physicians, would expect when the mesh was used for its normal and intended purpose.

91. The Products implanted in Plaintiffs were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. The use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. Biomechanical issues with the Products, including, but not limited to, the

propensity to contract or shrink inside the body, that in turn cause the surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

c. The propensity of the Products to degrade and fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and/or

d. The use of the Omega 3 coating decreases the PH of the abdominal cavity, results in a higher rate of infection and prevents tissue integration, resulting in injuries.

92. The C-QUR Mesh reached Plaintiffs' implanting surgeons and was implanted without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

93. The C-QUR Mesh failed to perform as safely as ordinary consumers and/or their physicians would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the C-QUR mesh outweigh its benefits. The design defects in the C-QUR mesh were not known, knowable and/or reasonably visible to Plaintiffs and/or their physicians, or discoverable upon any reasonable examination. The C-QUR mesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

94. The risks of the C-QUR Mesh significantly outweigh any benefits that Defendants contend could be associated with the product. The Omega 3 coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contract, migration, erosion and

rejection. The impermeable Omega 3 coating leads to seroma formation, provides a breeding ground for infection, and protects bacteria from being eliminate by the body's natural immune response. The Omega 3 coating also caused immunogenic responses and was known to be cytotoxic.

95. The Omega 3 coating of the C-QUR Mesh, which was marketed, promoted, and intended as a barrier against adhesion to the bowel was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. Once exposed, the mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the coating (to prevent adhesion to the bowel and internal viscera) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

96. The polypropylene mesh within the defective Omega 3 coating of the C-QUR Mesh was itself dangerous and defective, particularly when used in the manner intended by Defendants. The particular polypropylene material used in the C-QUR Mesh was substandard, adulterated, non-medical grade, and unreasonably subject to oxidative degradation within the body, further exacerbating adverse reactions once the Omega 3 coating degraded. When implanted adjacent to the bowel and other internal organs, as Defendants intended for C-QUR Mesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation, and bowel strangulation or hernia incarceration, and other injuries.

97. The appropriate treatment for complications associated with C-QUR Mesh often involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

98. The C-QUR Mesh was designed and intended for intraperitoneal implantation, which required the product to be placed in contact with internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

99. At the time the C-QUR Mesh was implanted in the Plaintiffs, there were safer, feasible alternative designs for hernia mesh products that would have prevented Plaintiffs' injuries.

100. The C-QUR Mesh cost significantly more than competitive products because of its unique Omega 3 coating, even though the Omega 3 coating provided no benefit to consumers and increased the risks to patients implanted with these devices.

101. The defective and unreasonably dangerous condition of the C-QUR Mesh was the proximate cause of the damages and injuries complained of by Plaintiffs.

102. As a direct and proximate result of the C-QUR Mesh's aforementioned design defects, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

103. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, selling and/or distributing defective products.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

104. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

105. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the Products implanted in Plaintiffs. The Products were defective in manufacture and construction when they left the hands of Defendants in that the manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

106. The Product(s) implanted in the Plaintiff named in the Short Form Complaint was not reasonably safe for the intended uses and was defective as described herein, as a matter of law, with respect to its manufacture, in that it deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff named in the Short Form Complaint.

107. The Products, as manufactured and constructed by Defendants, were unreasonably dangerous to end consumers, including Plaintiffs, and posed an unreasonable degree of risk, danger and harm to Plaintiffs.

108. The Products were expected to reach and did reach Plaintiffs' implanting surgeons and Plaintiffs without substantial change in the condition in which it was manufactured, supplied, distributed sold and/or otherwise placed in the stream of commerce.

109. The manufacturing defects in the Products implanted in the Plaintiffs were not known, knowable or readily visible to Plaintiffs' physicians or to Plaintiffs, nor were they discoverable upon any reasonable examination by Plaintiffs' physicians or Plaintiffs. The C-QUR

Mesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendants in accordance with the instructions for use and specifications provided by Defendants.

110. The Products implanted in Plaintiffs were different from the intended design and failed to perform as safely as products manufactured in accordance with the intended design would have performed.

111. The defective and unreasonably dangerous condition of the Product was a proximate cause of the damages and injuries suffered by the Plaintiff named in the Short Form Complaint.

112. As a direct and proximate result of the Product's aforementioned manufacturing defects as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

113. Defendants are strictly liable to the Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

114. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

115. Defendants manufacture, design, market, sell and/or otherwise place into the stream of commerce their C-QUR mesh.

116. The Product(s) implanted in the Plaintiff named in the Short Form Complaint was not reasonably safe for the intended uses and was defective as described herein, as a matter of law, due to the lack of appropriate and necessary warnings. As described herein, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks. Among other subjects, Defendants did not provide sufficient or adequate warnings regarding:

a. The cytotoxicity, immunogenic, and biologically incompatible nature of the Omega 3 coating;
b. The propensity of the Omega 3 coating to decrease the PH of the abdominal cavity and/or the blood;
c. The propensity of the Products to roll, curl, and deform upon insertion into the body;
d. The unusually high rate of infection associated with the Products;
e. The risks associated with the Omega 3 coating;
f. The frequency of recurrence due to a lack of tissue integration;
g. The Products' propensities to contract, retract, and/or shrink inside the body;
h. The Products' propensities for deterioration, degradation, fragmentation, and/or

disintegration;

i. The risk of chronic inflammation resulting from the Products;

j. The risk of chronic infections resulting from the Products;

k. The risk of recurrent, intractable pain resulting from the Products;

l. The need for corrective or revision surgery to adjust or remove the Products;

m. The frequency, severity, and duration of complications that could arise as a result of the implantation of the Products;

n. The hazards associated with the Products;

o. The Products' defects as described herein;

p. Treatment with these Products is no more effective than feasible, available alternatives;

q. Treatment with these Products exposes patients to greater risks than feasible, available alternatives;

r. Use of the Products puts the patient at a greater risk of requiring additional surgery than feasible, available alternatives;

s. Use of the Products makes any future abdominal surgery on the patient much more complex and dangerous than feasible, available alternatives;

t. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and/or

u. Complete removal may not result in complete resolution of the complications, including pain.

117. The Defendants failed to properly and adequately warn and instruct Plaintiffs and their treating physicians that C-QUR mesh was designed and/or manufactured in a way that could

cause injuries and damages, including lasting and permanent injuries. Defendants further failed to inform and/or warn Plaintiffs and their treating physicians with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive C-QUR Mesh.

118. The Defendants failed to properly and adequately warn and instruct Plaintiffs and their treating physicians as to the risks of the Defendants' C-QUR Mesh. To the contrary, Defendants withheld information from Plaintiffs and their treating physicians regarding the true risks related to implantation of their C-QUR mesh.

119. The Defendants failed to properly and adequately warn and instruct Plaintiffs and their treating physicians that inadequate research and testing of the C-QUR Mesh was done prior to C-QUR mesh being placed on the market and in the stream of commerce and that Defendants' lacked a safe, effective procedure for removal of the C-QUR Mesh once complications from the same arise.

120. The Defendants intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of C-QUR Mesh, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiffs.

121. Plaintiffs and their physicians were unaware of the defects and dangers of C-QUR Mesh, and were unaware of the frequency, severity and duration of the risks associated with the C-QUR Mesh.

122. Defendants' Instructions for Use provided with the C-QUR Mesh expressly understates and misstates the risks known to be associated specifically with the C-QUR Mesh by representing that the complications associated with C-QUR Mesh were the same as those "with

the use of any surgical mesh." No other surgical mesh sold in the United States has the dangerous and defective Omega 3 coating, which itself causes or increases the risks of numerous complications, including the prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the C-QUR Mesh.

123. Defendants' Instructions for Use failed to adequately warn Plaintiffs' physicians of numerous risks which Defendants knew or should have known were associated with the C-QUR Mesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

124. Defendants failed to adequately train or warn Plaintiffs or their physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

125. Defendants failed to adequately warn Plaintiffs or their physicians that the surgical removal of the C-QUR Mesh, in the event of complications, would leave the hernia unrepaired and would necessitate further medical treatment to attempt to repair the same hernia that the failed C-QUR Mesh was intended to treat.

126. Defendants represented to physicians that the Omega 3 coating would prevent or reduce adhesion, and expressly intended for the C-QUR Mesh to be implanted in contact with the bowel and internal organs. Defendants marketed and promoted the Products for said purpose. Defendants failed to warn Plaintiffs or their physicians that the Omega 3 coating prevented tissue

ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn Plaintiffs or their physicians that the Omega 3 coating was only temporary and therefore, at best, would provide only a temporary adhesion barrier and when the coating eventually degraded, the exposed polypropylene would become adhered to the bowel or tissue.

127. With respect to the complications that were listed in Defendants' warnings, Defendants failed to provide information or warnings regarding the frequency, severity, and duration of those complications, even though the complications associated with C-QUR Mesh were more frequent, more severe, and lasted longer than those with safer feasibly alternative hernia repair treatments.

128. If Plaintiffs and/or their physicians had been properly warned of the defects and dangers of C-QUR Mesh, and of the frequency, severity and duration of the risks associated with the C-QUR Mesh, Plaintiffs would not have consented to the implant, and Plaintiffs' physicians would not have implanted the C-QUR Mesh. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the C-QUR Mesh, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

129. The Defendants are strictly liable to the Plaintiff named in the Short Form Complaint for their wrongful conduct in failing to properly warn Plaintiffs and for designing, manufacturing, marketing, labeling, packaging, and/or selling a defective product.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

130. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

131. At the time of Plaintiffs' injuries, the Defendants' Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiffs. Additionally, the warnings, labels, and instructions were deficient.

132. Defendants' Products are dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

133. Plaintiffs from states where the common law, the Restatement of Torts (Second) and/or the Restatement of Torts (Third) are adopted, bring strict product liability claims under the common law, Section 402(A) of the Restatement of Torts (Second) and/or the Restatement of Torts (Third) against Defendants.

134. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert each of these claims against Defendants.

135. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

individually, jointly, severally, and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF EXPRESS WARRANTY

136. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

137. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce C-QUR Mesh.

138. In advertising, marketing and otherwise promoting C-QUR Mesh to physicians, hospitals and other healthcare providers, Defendants expressly warranted that their C-QUR Mesh was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting C-QUR Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to implant the Products in their patients.

139. With respect to the Plaintiff named in the Short Form Complaint, Defendants intended that C-QUR Mesh be implanted by his/her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. The Plaintiff named in the Short Form Complaint was in privity with Defendants.

140. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiffs that C-QUR Mesh was safe and fit for use by consumers, that it was of merchantable quality, that its risks, side effects and potential complications were minimal and comparable to other hernia mesh products, that it was adequately researched and

tested, and that it was fit for its intended use. Plaintiffs and their physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiffs were implanted with Defendants' C-QUR Mesh.

141. Defendant breached these express warranties because the Products implanted in the Plaintiff named in the Short Form Complaint were unreasonably dangerous, defective, and not as Defendants had represented.

142. Defendants breached express representations and warranties made to the Plaintiffs named in the Short Form Complaint, as well as his/her physicians and healthcare providers, with respect to the Products, including, but not limited to, the following particulars:

A. Defendants represented to Plaintiffs and their physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' C-QUR Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using C-QUR Mesh;

B. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' C-QUR Mesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that C-QUR Mesh was not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' C-QUR Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants

fraudulently concealed information, regarding the true efficacy of C-QUR Mesh.

143. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective product(s) implanted in the Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

144. At the time of making such express warranties, Defendants knew or should have known that Defendants' C-QUR Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiffs' rights, health and safety so as to warrant the imposition of punitive damages.

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145. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

146. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

147. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' C-QUR Mesh.

148. Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

149. Defendants impliedly warranted that their Products were of merchantable quality, safe and fit for the intended use of implantation in Plaintiffs and were properly and adequately tested prior to being placed in the stream of commerce.

150. When the Products were implanted in the Plaintiffs, they were being used for the ordinary purposes for which they were intended.

151. Defendants intended that their C-QUR Mesh be implanted for the purposes and in the manner that Plaintiffs' surgeons implanted the Products, in accordance with the instructions for use and product specifications provided by Defendants.

152. Defendants were aware that consumers, such as the Plaintiffs, would be implanted with C-QUR Mesh by their treating physicians in accordance with the instructions for use and product specifications provided by Defendants.

153. The Plaintiff named in the Short Form Complaint was a foreseeable user of Defendants' C-QUR Mesh and was in privity with Defendants.

Defendants breached implied warranties with respect to the C-QUR Mesh, including the following particulars:

A. Defendants represented to Plaintiffs and their physicians and healthcare

providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' C-QUR Mesh was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using C-QUR Mesh;

B. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' C-QUR Mesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the C-QUR Mesh was not safe, as safe as or safer than alternatives and other products available on the market; and

C. Defendants represented to Plaintiffs and their physicians and healthcare providers that the Defendants' C-QUR Mesh were more efficacious than other alternative procedures and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of C-QUR Mesh.

154. The Plaintiff named in the Short Form Complaint individually and/or by and through her physician, relied upon Defendants' implied warranties in consenting to have the Product(s) implanted.

155. In reliance upon Defendants' implied warranties, Plaintiffs' implanting surgeons used C-QUR Mesh to treat Plaintiffs in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

156. Defendants breached their implied warranties to Plaintiffs because the Products were not of merchantable quality, safe and fit for their intended use, as warranted, nor were they adequately tested prior to being placed in the stream of commerce.

157. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective product(s) in the body of the Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

158. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiffs' rights, health and safety, so as to warrant the imposition of punitive damages.

159. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiffs have experienced significant mental and physical pain and suffering, have sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, consortium, and have incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: FRAUDULENT CONCEALMENT

160. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

161. At all times relevant hereto, it was known or knowable to Defendants that their Products caused large numbers of complications. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its Products had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion. It was known or knowable to Defendants that the Products were not safe and effective. Defendants continued to represent that its Products were safe and effective.

162. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its Products, Defendants failed to disclose this information to the Plaintiffs, to their physicians, and to the public at large.

163. At all times relevant hereto, Defendants had the duty and obligation to disclose to Plaintiffs and their physicians the true facts concerning the Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiffs were implanted with Defendants' Products.

164. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety, and

efficacy of its Products;

b. Defendants knowingly made false claims about the safety and quality of its Products in documents and marketing materials;

c. Defendants fraudulently and affirmatively concealed the defective nature of the Products from the Plaintiffs.

165. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Products.

166. At all times relevant hereto, Defendants and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians with the intent to defraud, as alleged herein.

167. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Products, and their healthcare providers would dispense, prescribe, and recommend the Defendants' Products, and Plaintiffs justifiably acted or relied upon the concealed and/or non-disclosed facts to their detriment.

168. At all times relevant hereto, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized Defendants' Products in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiffs' physicians selecting Defendants' Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiffs, as patients.

169. As a direct and proximate result of this conduct, Plaintiffs were injured.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally, and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, an such further relief as the Court deems equitable and just.

COUNT IX: CONSTRUCTIVE FRAUD

170. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

171. Defendants are in a unique position of knowledge concerning the quality, safety, and efficacy of the Defendants' Products; knowledge that is not possessed by Plaintiffs or their physicians. Defendants thereby hold a position of superiority over Plaintiffs and their physicians.

172. Despite their unique and superior knowledge regarding the defective nature of the Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and the public concerning the severity and frequency of risks and dangerous inherent in the intended use of its Products, as compared to other products and forms of treatment.

173. Defendants have concealed and suppressed material information that would reveal that the Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

174. Upon information and belief, Defendants'' misrepresentation are designed to induce physicians to prescribe, dispense, recommend, and/or purchase the Defendants' Products. Plaintiffs and the medical community have relied upon Defendants' misrepresentations.

175. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their healthcare providers, and engaged in constructive fraud in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

176. As a proximate cause of the Defendants'' conduct, Plaintiffs have been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally, and in the alternative, request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

177. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

178. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment

179. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicated that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

180. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and

their relationship to the Products was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suits were filed well within the applicable statutory limitations period.

181. The running of the statute of limitations in this cause of action is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

COUNT XI: NEGLIGENT MISREPRESENTATION

182. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

183. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that its Products had not been adequately tested and found to be a safe and effective treatment. The representations made by Defendants were, in fact, false.

184. Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Products' high risk of unreasonable and dangerous adverse side effects.

185. Defendants breached their duty in representing that the Defendants' Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical community.

186. As a foreseeable, direct, and proximate result of the negligent misrepresentation of Defendants, as set forth herein, Defendants knew, and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk—and/or higher than acceptable risk, and/or higher than reported and represented risk—of adverse side effects, including, but not limited to, pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

187. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

188. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

189. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold the Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Products from Plaintiffs, and carelessly and negligently misrepresented the

quality, safety and efficacy of the Products.

190. Defendants carelessly and negligently concealed the harmful effects of the Products from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

191. As a result of Defendants carelessly and negligently concealing the harmful effects of the Product, Plaintiffs' symptoms and injuries not taken seriously and/or were not adequately treated on multiple occasions.

192. Plaintiffs suffered severe emotional distress due to their injuries and symptoms not being taken seriously and/or not being adequately treated.

193. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of being implanted with the Products sold and distributed by Defendants.

194. As a direct and proximate result of Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them individually, jointly, and severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

195. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

196. Plaintiffs, by and through their treating physicians, were implanted with Defendants' C-QUR Mesh primarily for the personal use and purpose of treating their physical medical conditions and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

197. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

198. Defendants engaged in unfair methods of competition and/or deceptive acts or practices that were prescribed by law, including the following:

A. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.

B. Advertising goods or services with the intent not to sell them as advertised; and,

C. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

199. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Products. Each aspect of Defendants' conduct combined to artificially create sales of Defendants' Products.

200. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, marketing, promotion, and sale of

surgical mesh products.

201. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or otherwise been implanted with Defendants Products, and would not have suffered permanent physical injury as described herein and incurred related medical costs and injuries.

202. Defendants' deceptive, unconscionable and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes.

203. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statues.

204. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statutory provisions of the Plaintiffs' respective states.

205. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

206. Defendants violated the statutes enacted in these States to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Products were fit to be used for its intended purpose, while, in fact, the Products were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

207. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

208. Defendants had actual knowledge of the defective and dangerous condition of Defendants' Products and failed to take any action to cure such defective and dangerous conditions to the detriment of Plaintiffs and other consumers.

209. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining whether to use Defendants' Products.

210. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

211. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

212. As a direct and proximate result of Defendants' violations of the consumer protection laws, Plaintiffs have sustained economic losses and other damages, and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIV: GROSS NEGLIGENCE

213. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

214. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs such that Plaintiffs will seek, at the appropriate time under governing law, the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs; or, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually and subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, welfare of others, or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

215. Plaintiffs relied on the representation and suffered injuries as a proximate result of this reliance.

216. Plaintiffs therefore will seek to assert claims for exemplary damages, at the appropriate time, under governing law in an amount within the jurisdictional limits of the Court.

217. Plaintiffs further allege that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaged in such misconduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV: UNJUST ENRICHMENT

218. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 74 of this Master Complaint as if each were set forth fully and completely herein.

219. Defendants are, and at all times relevant were, manufacturers, sellers, and/or suppliers of the Products.

220. Plaintiffs paid for Defendants' Products for the purpose of medical treatment.

221. Defendants have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of Defendants' Products.

222. Plaintiffs have not received the safe and effective medical devices for which they paid.

223. It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device, as represented by Defendants

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI: LOSS OF CONSORTIUM

224. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 214 of this Master Complaint as if each were set forth fully and completely herein.

225. As a direct and proximate result of the above-described injuries sustained by the

Plaintiff named in the Short Form Complaint, where applicable, his/her spouse named in the Short Form Complaint has suffered a loss of spousal consortium, companionship, society, affection, services, and support.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as this Court deems equitable and just.

COUNT XVII: PUNITIVE OR ENHANCED COMPENSATORY DAMAGES

226. Plaintiffs re-allege and incorporate by reference every paragraph of this Master Complaint as if each were set forth fully and completely herein.

227. Defendants sold their Products to the healthcare providers of the Plaintiff named in the Short Form Complaint, and other healthcare providers throughout the United States without doing adequate testing to ensure that the Products were reasonably safe and effective for permanent, human implantation. Defendants continued to manufacture and sell C-QUR Mesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

228. Even though Defendants have other hernia mesh devices that do not present the same risks as the C-QUR Mesh, Defendants developed, designed, and sold C-QUR Mesh, and continue to do so, because the C-QUR Mesh has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective C-QUR Mesh, including the risk of failure and serious injury, such as suffered by Plaintiffs.

229. At all times relevant hereto, Defendants knew or should have known that C-QUR Mesh was inherently more dangerous with respect to the risks of foreign body response, allergic

reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

230. Defendants willfully and recklessly failed to avoid those consequences and, in doing so, Defendants acted intentionally, maliciously, and recklessly without regard to the safety of those persons who might foreseeably be harmed by the C-QUR product, including the Plaintiff named in the Short Form Complaint.

231. At all times material hereto, Defendants attempted to misrepresent and did intentionally and knowingly misrepresent facts concerning the safety of their C-QUR Mesh products.

232. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety and efficacy of the C-QUR Mesh, which deprived Plaintiffs and their implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use C-QUR mesh.

233. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that the Defendants' C-QUR Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

234. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that C-QUR Mesh can cause debilitating and potentially life threatening side effects with greater frequency than safer alternative products and/or methods of treatment and

recklessly failed to advise the medical community and the general public, including Plaintiffs, of the same.

235. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complication caused by and associated with C-QUR Mesh.

236. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of C-QUR Mesh with its increased risk of side effects and serious complications, Defendants continue to aggressively market C-QUR Mesh to the medical community and to consumers without disclosing the true risk of such complications and side effects.

237. At the time the Plaintiff named in the Short Form Complaint was implanted with C-QUR Mesh and since that time, Defendants knew that C-QUR Mesh was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell C-QUR Mesh so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by C-QUR Mesh to members of the public including Plaintiffs.

238. At all times material, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with C-QUR Mesh in order to ensure continued and increased sales and profits to the detriment of the public, including Plaintiffs.

239. Defendants' conduct, acts and omissions, as described herein, are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious

indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs, and economic damages including past and future lost earnings and/or earning capacity, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. The costs of these proceedings, including past a future cost of the suit incurred herein;

vi. All ascertainable economic damages;

vii. Survival damages (if applicable);

viii. Wrongful death damages (if applicable);

ix. Prejudgment interest on all damages as is allowed by law; and

x. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Jonathan D. Orent
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